



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Cardiovascular and Renal Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cardiovascular and Renal Drugs Advisory Committee. This meeting was announced in the Federal Register of February 27, 2015 (80 FR 10700). The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, CRDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 27, 2015, FDA announced that a meeting of the Cardiovascular and Renal Drugs Advisory Committee would be held on April 15, 2015. On page 10700, in the first column, the Agenda portion of the document is changed to read as follows:

The committee will discuss the new drug application (NDA) 204958, cangrelor injection, submitted by The Medicines Company, for the proposed indication of reduction of thrombotic cardiovascular events in patients with coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI)--(PCI refers to the opening of narrowed blood vessels supplying the heart muscle by a balloon inserted through an artery puncture with or without a stent) who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable (P2Y12 is a protein involved in blood clotting. Inhibiting this protein is a key mechanism of action of cangrelor).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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